PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 5/00, 5/32, 5/178 — A1

(11) International Publication Number: **WO 97/42989**

(43) International Publication Date: 20 November 1997 (20.11.97)

(21) International Application Number: PCT/IL97/00155

(22) International Filing Date: 11 May 1997 (11.05.97)

(30) Priority Data:
118223 12 May 1996 (12.05.96) IL

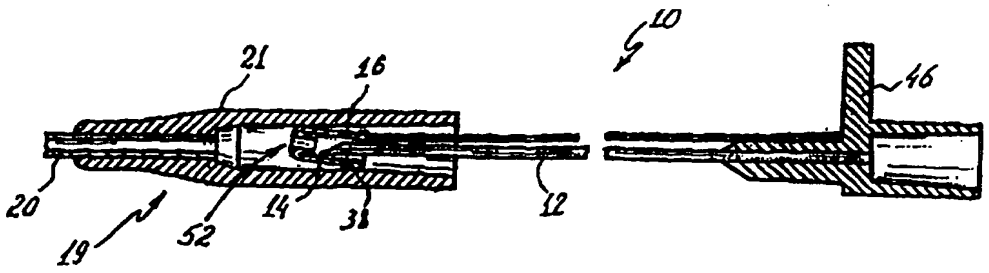
(71)(72) Applicant and Inventor: POPOV, Sergey [IL/IL]; P.O. Box 4583, 84144 Beer Sheva (IL).

(74) Agent: BEN-DAVID, Yirmiyahu, M.; Har Hotzvim Hi-Tech Park, P.O. Box 45087, 91450 Jerusalem (IL).

(81) Designated States: CN, JP, RU, US, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: CATHETER PLACEMENT DEVICE



(57) Abstract

This invention is a catheter placement device (10) having a catheter unit which includes a catheter (20) for insertion into a blood vessel, a catheter hub (21) attached to the catheter, a needle unit which includes a needle (12) inserted within the catheter unit, and needle hub (46) attached to the needle, wherein the needle is shielded upon withdrawal from the catheter unit.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

CATHETER PLACEMENT DEVICE

FIELD OF THE INVENTION

The present invention relates generally to apparatus for the placement of catheters in blood vessels by use of a needle, and, particularly, to such apparatus which includes safety devices for preventing accidental pricking of another person by the needle, after withdrawal from a subject.

BACKGROUND OF THE INVENTION

Various devices for the placement of catheters into blood vessels, are known. A common feature of these devices is their use of a needle carrier which is located within and protrudes form the front end of the catheter. The entry puncture through the skin and into a selected blood vessel, is provided by the front end of the needle. As the needle, having an increasing diameter, is inserted progressively further into the blood vessel, the catheter is introduced therein. Following catheter tube introduction, the needle is generally removed, and during this removal and prior to disposal, there exists a risk of accidental pricking by the needle tip, and infection of the operator. Accordingly, various devices for automatically shielding the needle tip during its removal from the catheter unit have been developed, and are in widespread use.

An indication of the state of the art is provided by US Patents No. 4,205,675; 5,215,528; 5,234,411 and 5,462,533.

US Patent No. 5,215,528 describes an assembly for introducing a catheter into a blood vessel is provided. The assembly includes a needle hub having a needle secured thereto. The needle includes an elongate shaft having a beveled tip. A portion of the needle shaft adjacent to the tip has a relatively large outside diameter. The shaft diameter of this portion exceeds the diameter, of the shaft portion adjoining the tip and the diameter of the shaft portion extending between the enlarged shaft portion and the needle hub. A catheter is mounted over the shaft of the needle, and includes an inner surface which bears against the enlarged shaft portion. A substantially leak-proof seal is thereby provided between the catheter and the needle shaft. A needle tip cover is slidably mounted to the needle shaft and is engageable with the enlarged portion of the shaft to prevent its removal therefrom. The catheter is releasably mounted to the needle tip cover.

There is also disclosed a catheter placement device, in US Patent No. 5,562,633, to Wozencroft. The described catheter placement device comprises an introducing needle

having a pointed tip for introducing a catheter into a desired position in a patient's body; a needle hub for mounting the needle so that the needle extends through an axial bore in the catheter during introduction of the catheter into the patient's body and so that the needle can subsequently be withdrawn from the catheter bore leaving the catheter in position in the patient's body; and a needle tip protector on the needle for shielding the needle tip when the needle has been withdrawn from the catheter bore.

The needle tip protector includes a guard element which is held against a resilient bias in a cocked position to one side of the catheter while the catheter is introduced into the patient's body and which, on subsequent withdrawal of the needle from the catheter bore, is moved laterally by resilient action from the cocked position into a guard position in which it shields the needle tip.

SUMMARY OF THE INVENTION

The present invention seeks to provide an improved catheter placement device which is characterized by a simplified construction, and improved safety over known devices.

There is thus provided, in accordance with a preferred embodiment of the present invention, a catheter placement device having a catheter unit which includes a catheter for insertion into a blood vessel and having front and rear ends and a longitudinal axis; and catheter hub apparatus attached to the rear end of the catheter; and a needle unit having initial, intermediate and final positions with respect to the catheter unit, in the initial position the needle unit being in operative association with the catheter unit for introduction of the catheter tube into a patient's blood vessel, and in the final position, the needle unit not being in operative association with the catheter unit.

In accordance with the present invention, the needle unit includes a catheter introduction needle having a longitudinal axis; a needle hub attached to the rear end of the needle and operative to support the needle in the catheter tube, in coaxial alignment therewith, when the needle unit is in the initial position; a needle tip capping element for selectable positioning in overlapping relation with the needle tip, and having front shielding

apparatus and lateral shielding apparatus associated therewith; and resilient locking apparatus arranged in force transfer association with the capping element and a predetermined one of the needle hub and the needle.

In the initial position of the needle unit, the needle is supported by the needle hub in the catheter tube, such that the needle tip protrudes from the front end of the catheter tube, and the front shielding apparatus is located laterally with respect to the needle in non-overlapping relation with the needle tip, and in response to a rearward withdrawal force applied to the needle hub, the needle is operative to move in a rearward direction relative to the capping element so as to tension the resilient locking apparatus, wherein, as the needle tip moves rearwardly of the capping element, the locking apparatus is operative to cause a relative lateral movement between the needle tip and at least the front shielding apparatus so that the front shielding apparatus intersects with the longitudinal axis of the needle, such that the needle unit is in the intermediate position.

In response to the rearward movement of the needle tip relative to the capping element, the resilient locking apparatus is operative to apply a generally rearward locking force to the capping element, thereby to position the lateral shielding apparatus in the overlapping position with respect to the needle tip, such that the front shielding portion and the lateral shielding portion overlap the needle tip, such that the needle unit is in the final position.

Additionally in accordance with a preferred embodiment of the invention, the needle unit also includes linkage apparatus associated with the needle hub and the capping element, and operative, in response to the tensioning of the locking apparatus, to apply a lateral displacement force to a predetermined one of the capping element and the needle, thereby causing the relative lateral movement between the needle tip and at least the front shielding apparatus.

Further in accordance with a preferred embodiment of the invention, the linkage apparatus is further operative, when the needle unit is in the intermediate and final positions, to prevent substantial forward movement of the capping element relative to the needle tip.

Additionally in accordance with a preferred embodiment of the invention, the linkage apparatus includes an elongate linkage element having front and rear ends, wherein the front end is connected to the capping element, and the rear end is associated with the needle hub, and preferably is connected thereto,

Further in accordance with a preferred embodiment of the invention, at least one of the elongate linkage member, the needle hub, and the needle, is flexible, preferably

resilient, thereby permitting the relative lateral movement between the needle tip and at least the front shielding apparatus.

In accordance with one embodiment of the invention, the first lateral shielding portion is rigid, and the capping element has a generally tubular shape having a front end in which is defined an opening through which the needle extends when the needle unit is in the initial position, and wherein the second lateral shielding portion defines a rearward facing ledge.

Additionally in accordance with a preferred embodiment of the invention, the elongate linkage element is connected to the capping element at a predetermined lever arm distance from the cover axis such that the tensioning of the locking apparatus gives rise to a rotation of the capping element, thereby to cause the relative lateral movement between the needle tip and at least the front shielding apparatus.

In accordance with an alternative embodiment of the invention, the first lateral shielding portion is resilient, and the first shielding portion is operative to urge the second lateral shielding portion so as to apply an inward urging force to the needle when the needle is in the initial position, such that, as the needle tip moves rearwardly of the second lateral shielding portion, the front shielding apparatus and the second lateral shielding portion undergoes a lateral movement relative to the needle tip so that the front shielding apparatus intersects with the longitudinal axis of the needle.

Further in accordance with a preferred embodiment of the invention, the first and second lateral shielding portions define a shielding plane and the needle unit further includes guide apparatus for preventing the needle from moving laterally with respect to the plane.

Additionally in accordance with a preferred embodiment of the invention, the needle hub has a protruding portion in which is formed a guide opening through which the elongate linkage element extends, and the rear end of the elongate linkage member is arranged for selectable engagement with the needle hub, and includes a resilient portion disposed between the rear end of the linkage member and the needle hub which is operative to elastically resist a rearward withdrawal force and to permit completion of a rearward stroke in the presence of a rearward force of greater magnitude, and which, upon removal of the rearward force, is operative to urge the needle in a generally forward direction, thereby to cause the mutual locking engagement of the needle tip and the capping element.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be more fully understood and appreciated from the following detailed description, taken in conjunction with the drawings, in which:

Fig. 1A is a side-sectional view of a catheter placement device, constructed and operative in accordance with a preferred embodiment of the invention, seen in an initial position, prior to placement of the catheter;

Figs. 1B and 1C are further views of the device of Fig. 1A, but wherein the needle and needle hub are shown in a intermediate positions;

Fig. 1D is a side view of a needle unit seen in Figs. 1A-1C, in a final, capped position;

Fig. 2 is an enlarged side-sectional view of the capping element seen in Figs. 1A-1D;

Fig. 3 is a side view of a capped needle, constructed in accordance with an alternative embodiment of the invention, in which the needle hub is flexible;

Fig. 4 is a side-sectional view of a catheter placement device, constructed and operative in accordance with an additional embodiment of the invention, in which the needle is flexible, and wherein the needle and needle hub are shown in a partially withdrawn position;

Fig. 5 is a side view of the needle unit of Fig. 4, seen in a capped position after withdrawal from the catheter and catheter hub;

Fig. 6 is a side-sectional view of a catheter placement device, constructed and operative in accordance with yet a further embodiment of the invention, in which a linkage element and capping element are provided as an integral, elongate member, and wherein the needle and needle hub are shown in an initial position; and

Fig. 7 is a side view of the needle unit of Fig. 6, seen in a capped position after withdrawal from the catheter and catheter hub.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to Figs. 1A-1D, there is shown a catheter placement device, referenced generally 10, constructed and operative in accordance with a preferred embodiment of the invention. Device 10 has an introducing needle 12, which may be of a conventional type, having a needle tip 14 at its front end, and a needle tip cap or capping element 16, shown in detailed cross-section in Fig. 2, located in association with a rear portion of needle 12, shown at 18 (Fig. 1A). Needle 12 is movable relative to needle tip cap 16 between an initial position, shown in Fig. 1A, in which needle tip 14 protrudes from

a front end 19 of catheter 20, in order to provide introduction thereof into a selected blood vessel of a patient's body, and a final position, shown in Fig. 1D. In this position, needle tip 14 is covered by needle tip cap 16. Catheter 20 is attached to a hub 21, which may be of any known type.

Referring now particularly to Fig. 2, it is seen that, in the illustrated embodiment, cap 16 is tubular shaped, having an interior opening 22, through which needle 12 extends. Cap 16 has a rear opening 24 of a relatively large diameter, and a front shielding portion 26, whose purpose will be understood from the following description. Front shielding portion 26 is formed at the front end of cap 16, in which is also provided an opening 28 of a smaller diameter, typically slightly larger than that of needle 12, so that the needle is just able to pass therethrough. Front shielding portion 26 is formed, as seen, so as to define first and second lateral shielding portions, referenced 30 and 31. In the illustrated embodiment, first lateral shielding portion 30 is a generally cylindrical side wall of cap 16, while second lateral shielding portion 31 is a truncated generally conical portion terminating in a rearward facing ledge 32. Lateral shielding portions 30 and 31 define therebetween a V-shaped notch 34. In the present embodiment, therefore, front shielding portion 26 is provided to shield or cover needle tip 14, the described V-notch preventing lateral displacement of cap 16 relative to needle tip 14, once the needle tip 14 has become fully engaged therewith. Cap 16 preferably is formed with a flange 38 on its rear end, serving to position cap 16 axially within the catheter hub 21, and further serving to prevent dislodgment of the cap 16 during a rearward stroke of the needle 12, during withdrawal of the needle from catheter 20, until completion of the rearward stroke. This is described below in greater detail.

There is also provided apparatus for preventing rear displacement of cap 16 relative to needle 12, when in the position, as seen in Fig. 1D. This is provided by way of an elongate, flexible linkage element or drawbar 40, attached by its front end 42 to flange 38 of cap 16, and by its rear end 44, to a needle hub 46, which, in turn, is rigidly attached to rear portion 18 of needle 12. The front end 42 of linkage element 40 is anchored to cap 16 at an anchor location 48 which is located eccentrically with respect to the longitudinal axis 50 (Fig. 2) of cap 16. When a pulling force is applied to cap 16 via linkage element 40, this eccentricity results in a slight rotation of the cap 16, thereby causing a lateral displacement of front shielding element 26, as well as the remainder of cap 16, relative to needle tip 14.

In the present embodiment, flexible linkage element 40 and cap 16 are formed as an integral molded plastic member, although element 40 may alternatively be formed as a nylon thread or cord element, for example, appropriately fastened to needle hub 46 and cap 16.

Use of the catheter placement device 10, is as follows:

Initially, catheter placement device 10 is in the position shown in Fig. 1A, such that needle tip 14 protrudes from the front end 17 of catheter 20. As known in the art, catheter 20 is then introduced into a selected blood vessel using needle 12 as a carrier.

Referring now to Fig. 1B, after introduction of catheter 20 into a selected blood vessel, needle 12 is withdrawn from catheter 20 by grasping catheter hub 21 in one hand, while exerting a rearward pulling force on the needle 12, via needle hub 46. Application of this rearward force to needle hub 46 causes it to disengage from catheter hub 21, as seen in the drawing, and further causes a gradual longitudinal sliding withdrawal of needle 12 through catheter 20 and through opening 28 of cap 16, while cap 16 is fully retained in its initial position, as seen in Figs. 1A and 1B, by virtue of the frictional engagement between flange 38 and catheter hub 21, in the present example. As needle hub 46 and needle 12 continue to be withdrawn linkage element 40 is extended, until it becomes taut, as shown in Figs. 1B and 1C.

The length of linkage element 40 is such that as it becomes completely extended, the needle tip 14 passes to the rear of ledge 32 in cap 16, as seen in Fig. 1C. Due to the flexibility in linkage element 40, needle 12 is permitted to drop slightly inside cap 16, towards first shielding portion 30, defined by the side wall of cap 16. At this intermediate stage, the pulling force applied to needle 12 and linkage element 40 is of a magnitude that is sufficient to completely withdraw cap 16 from the catheter hub 21, such that the entire needle unit, referenced generally 52, which includes the needle 12, needle hub 46, linkage element 40 and cap 16, becomes completely separated from catheter unit 19, which includes catheter 20 and catheter hub 21.

Preferably, linkage element 40 is made of a resilient material, such that, upon release of the cap from the catheter hub 21, linkage element 40 retracts slightly, thereby applying a "locking force" which causes a locking engagement of needle tip 14 in the V-notch 34 of cap 16.

It will be appreciated, however, that even if linkage element 40 were not resilient, such that the described locking force were not to be applied, as soon as needle tip 14 passes to the rear side of ledge 32, such that the needle tip drops, a relative longitudinal displacement of either the needle 12 or the cap 16 so as to cause engagement therebetween, would cause needle tip 14 to engage a rearward facing portion of the cap 16, so as to prevent the needle tip 14 from passing forward through the front opening 26.

Referring now to Fig. 3, there is seen a needle unit, referenced generally 152, which is generally similar to that shown and described above in conjunction with Figs. 1A-1D, and

is thus not specifically described again herein except as required for description of differences between needle unit 52 and the needle unit 152. Accordingly, portions of the needle unit 152 having counterpart portions in the embodiment of Figs. 1A-1D, are denoted in Fig. 3 by reference numerals having an additional prefix "1," and are not specifically described again herein.

Needle unit 152 is constructed and operates similarly to unit 52 (Figs. 1A-1D), except that, in the present embodiment, a resilient locking force, as described above, is applied by providing needle hub 146 as a flexible, resilient member. This is done by forming needle hub 146 of a suitable polymer material, and, preferably, by providing therein a weakened portion, such as by means of a notch 154, thereby forming an integral hinge. Accordingly, application of a pulling force so as to cause withdrawal of the entire needle unit 152 from the catheter hub (not shown), causes an upper protruding portion 156 of hub 146 to bend forwardly, as seen in outline in Fig. 3. A subsequent removal of the pulling force enables upper hub portion 156 to straighten, thereby applying a rearward force to cap 116 so as to force it into locking engagement with needle tip 114.

Referring now to Fig. 4, there is seen a catheter placement device 210, having a needle unit 252, shown in Fig. 5 in a fully withdrawn, locked position. Device 210 is generally similar to that shown and described above in conjunction with Figs. 1A-1D, and is thus not specifically described again herein except as required for description of differences between needle unit 252 and the needle unit 52 (Figs. 1A-1D). Accordingly, portions of the catheter placement device 210 having counterpart portions in the embodiment of Figs. 1A-1D, are denoted in Figs. 4 and 5 by reference numerals having an additional prefix "2," and are not specifically described again herein, except as necessary to understand the present embodiment.

Device 210 and needle unit 252 are constructed and operate similarly to device 10 and needle unit 52 (Figs. 1A-1D), except that, in the present embodiment, a resilient locking force, as described above, is applied by providing forming needle 212 from a flexible material, such as a suitable polymer. Accordingly, application of a pulling force so as to cause withdrawal of the entire needle unit 252 from catheter hub 221, as shown in Fig. 4, causes needle 212 to flex, as shown. Subsequent removal of the pulling force enables a partial straightening of needle 212, thereby bringing the cap 216 and needle tip 214 into locking engagement. It will, of course, be appreciated that the extent to which needle 212 flexes upon withdrawal, and the extent to which it is permitted to straighten, depend on the length of linkage element 240 which, in the present embodiment, is flexible, but has no significant elasticity.

In the present embodiment, due to the fact that needle 212, itself, flexes, and the locking force is thus applied therealong, and due to the relative shortness of linkage element 240, it may not be necessary to form a V-notch in the rearward facing surface 230 (Fig. 5) of cap 216, although it is preferable.

Referring now to Figs. 6 and 7, there is shown a catheter placement device, referenced generally 310, constructed and operative in accordance with yet a further embodiment of the present invention. Components of the illustrated device 310 having counterpart components that have been shown and described hereinabove in conjunction with any of devices 10, 110 or 210, are denoted in Figs. 6 and 7 by similar reference numerals, but with the addition of a prefix "3", and are not specifically described again herein.

Catheter placement device 310 is provided with a movably mounted flexible linkage rod or drawbar 360 which, as opposed to previous embodiments of the invention described above, is not attached to needle hub 346. Rather, needle hub 346 has a protrusion 362 having a guide opening 364 formed therein which is large enough to permit free sliding motion of rod 360 therethrough. There is also provided a resilient urging portion 366, which, in the present embodiment, is provided as an integral portion of linkage rod 360.

A front portion 368 of rod 360 has a wavelike configuration, and has formed therein openings 370, 372 and 374, which serve as a guide for needle 312. A front portion 376 of rod 360 is configured as an integral cap portion, and defines a first, resilient, lateral shielding portion 330 and a second lateral shielding portion 331, which form between them a rear facing V-notch 334, which serves for selectable engagement and locking of needle tip 314. Rod 360 is formed so that in an at rest position, front portion 376 extends generally inwardly, such that, once rod 360, needle 312 and needle hub 346 are assembled, and in an initial position, ledge 332 is in generally inwardly urging abutting engagement with a rear portion 318 of the needle 312.

In the present example, rod 360 is initially locked in an axial opening 378 of catheter hub 321, by virtue of frictional engagement of outward facing rod portions 380 and 382 with an inward-facing surface of catheter hub 321. Preferably, rod 360, front portion 376, and resilient urging portion 366 are made integrally from a single portion of flexible metal, or from a suitable plastic molding.

When needle 312 and needle hub 346 are withdrawn from catheter hub 321, after the catheter 320 is introduced into a patient's blood vessel, the needle hub 346 moves rearwardly along rod 360 until hub protrusion 362 engages a front portion 384 of urging portion 366. At this stage, the needle tip 314 is still located forwardly of front portion 376,

such that ledge 332 thereof presses laterally against a side portion of needle 312, under the urging force of resilient first lateral shielding portion 330. In order to cause engagement of the needle tip 314 with notch 332, a force has to be applied so as to overcome the forward urging force providing by urging portion 366 onto needle hub protrusion 362.

Accordingly, further rearward displacement of needle 312, under a force sufficient to overcome the urging force of urging portion 366, is sufficient to move needle tip 314 rearwardly past ledge 332, into an intermediate position, thereby disengaging therefrom and enabling second shielding portion 331 and ledge 332 to move laterally inward under the urging force of first shielding portion 330, thereby to extend laterally across and to cover needle tip 314. A further rearward force applied to needle hub 346 and transmitted to rod 360 via urging portion 366 is applied in order to overcome the frictional resistance between outward facing rod portions 380 and 382 and an inward-facing surface of catheter hub 321, thereby to enable complete withdrawal and disengagement of needle hub 346 and rod 360 from the catheter hub 321.

Subsequently, with the release of externally applied forces to needle hub 346 and urging portion 366, front portion 384 of urging portion 366 extends so as to slightly recover its original shape, thereby applying a forward force onto the needle hub 346. This force is transferred to needle 312, causing a forward displacement thereof relative to ledge 332, thereby locking together needle tip 314 and rod front portion 376.

In the present embodiment, the first and second lateral shielding portions 330 and 331 define a shielding plane, and openings 370, 372 and 374, formed in front portion 368 of rod 360, and which serve as a guide for needle 312, serve also to prevent needle 312 from moving laterally with respect to the shielding plane, thereby preventing needle tip 314 from being accidentally released sideways, once the needle tip 314 and needle unit 352 are locked in a final position.

It will be appreciated by persons skilled in the art that the scope of the present invention is not limited by what has been specifically shown and described hereinabove, merely by way of example. Rather, the scope of the invention is limited solely by the claims, which follow.

CLAIMS

1. A catheter placement device which comprises:

a catheter unit which comprises:

a catheter for insertion into a blood vessel and having front and rear ends and a longitudinal axis; and

catheter hub means attached to said rear end of said catheter; and

a needle unit having initial, intermediate and final positions with respect to said catheter unit, in said initial position said needle unit being in operative association with said catheter unit for introduction of said catheter tube into a patient's blood vessel, and in said final position, said needle unit not being in operative association with said catheter unit, wherein said needle unit comprises:

a catheter introduction needle having a longitudinal axis;

a needle hub attached to said rear end of said needle and operative to support said needle in said catheter tube, in coaxial alignment therewith, when said needle unit is in said initial position;

a needle tip capping element for selectable positioning in overlapping relation with said needle tip, and having front shielding means and lateral shielding means associated therewith; and

resilient locking means arranged in force transfer association with said capping element and a predetermined one of said needle hub and said needle,

wherein, in said initial position of said needle unit, said needle is supported by said needle hub in said catheter tube, such that said needle tip protrudes from said front end of said catheter tube, and said front shielding means is located laterally with respect to said needle in non-overlapping relation with said needle tip, and

in response to a rearward withdrawal force applied to said needle hub, said needle is operative to move in a rearward direction relative to said capping element so as to tension said resilient locking means, wherein, as said needle tip moves rearwardly of said capping element, said locking means is operative to cause a relative lateral movement between said needle tip and at least said front shielding means so that said front shielding means intersects with said longitudinal axis of said needle, such that said needle unit is in said intermediate position,

and wherein said resilient locking means, in response to said rearward movement of said needle tip relative to said capping element, is operative to apply a generally rearward locking force to said capping element, thereby to position said lateral shielding means in said overlapping position with respect to said needle tip, such that said front shielding

portion and said lateral shielding portion overlap said needle tip, such that said needle unit is in said final position.

2. A catheter placement device according to claim 1, wherein said needle unit also comprises linkage means associated with said needle hub and said capping element, and operative, in response to said tensioning of said locking means, to apply a lateral displacement force to a predetermined one of said capping element and said needle, thereby causing said relative lateral movement between said needle tip and at least said front shielding means.

3. A catheter placement device according to claim 2, wherein said linkage means is further operative, when said needle unit is in said intermediate and final positions, to prevent substantial forward movement of said capping element relative to said needle tip.

4. A catheter placement device according to claim 2, wherein said resilient locking means includes said linkage means.

5. A catheter placement device according to claim 2, wherein said linkage means comprises an elongate linkage element having front and rear ends, wherein said front end is connected to said capping element, and said rear end is associated with said needle hub.

6. A catheter placement device according to claim 5, wherein elongate linkage element is connected to said needle hub.

7. A catheter placement device according to claim 6, wherein said needle hub includes a protruding portion, and said elongate linkage element is connected to said protruding portion.

8. A catheter placement device according to claim 6, wherein at least one of said elongate linkage member, said needle hub, and said needle, is flexible, thereby permitting said relative lateral movement between said needle tip and at least said front shielding means.

9. A catheter placement device according to claim 7, wherein at least one of said

elongate linkage member, said needle hub, and said needle, is a resilient member.

10. A catheter placement device according to claim 5, wherein said front shielding means and said front end of said elongate linkage element are connected to said lateral shielding means.

11. A catheter placement device according to claim 10, wherein said lateral shielding means comprises first and second lateral shielding portions, and said front end of said elongate linkage element is connected to said first lateral shielding portion.

12. A catheter placement device according to claim 11, wherein said first lateral shielding portion is rigid.

13. A catheter placement device according to claim 11, wherein said first lateral shielding portion is resilient.

14. A catheter placement device according to claim 12, wherein said capping element has a generally tubular shape having a front end in which is defined an opening through which said needle extends when said needle unit is in said initial position, and wherein said second lateral shielding portion defines a rearward facing ledge.

15. A catheter placement device according to claim 12, wherein said elongate linkage element is connected to said capping element at a predetermined lever arm distance from said cover axis such that said tensioning of said locking means gives rise to a rotation of said capping element, thereby to cause said relative lateral movement between said needle tip and at least said front shielding means.

16. A catheter placement device according to claim 5, wherein said capping element and said elongate linkage element are formed integrally.

17. A catheter placement device according to claim 5, wherein said capping element, said elongate linkage element and said needle hub are formed integrally.

18. A catheter placement device according to claim 13, wherein said first shielding portion is operative to urge said second lateral shielding portion so as to apply an inward

urging force to said needle when said needle is in said initial position, such that, as said needle tip moves rearwardly of said second lateral shielding portion, said front shielding means and said second lateral shielding portion undergoes a lateral movement relative to said needle tip so that said front shielding means intersects with said longitudinal axis of said needle.

19. A catheter placement device according to claim 13, wherein said first and second lateral shielding portions define a shielding plane and said needle unit further comprises guide means for preventing said needle from moving laterally with respect to said plane.

20. A catheter placement device according to claim 13, wherein said elongate linkage element has formed therein a wavelike portion connected to said first lateral shielding portion, and said guide means comprises a plurality of axially aligned openings through which said needle extends when said needle unit is in said initial position.

21. A catheter placement device according to claim 5, wherein said needle hub has a protruding portion in which is formed a guide opening through which said elongate linkage element extends.

22. A catheter placement device according to claim 21, wherein said rear end of said elongate linkage member is arranged for selectable engagement with said needle hub, and comprises a resilient portion disposed between said rear end of said linkage member and said needle hub which is operative to elastically resist a rearward withdrawal force and to permit completion of a rearward stroke in the presence of a rearward force of greater magnitude, and which, upon removal of said rearward force, is operative to urge said needle in a generally forward direction, thereby to cause said mutual locking engagement of said needle tip and said capping element.

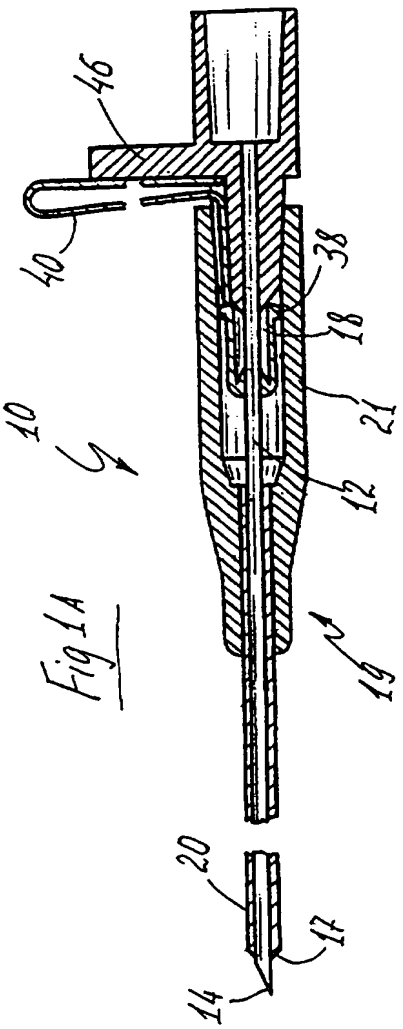


Fig 1A

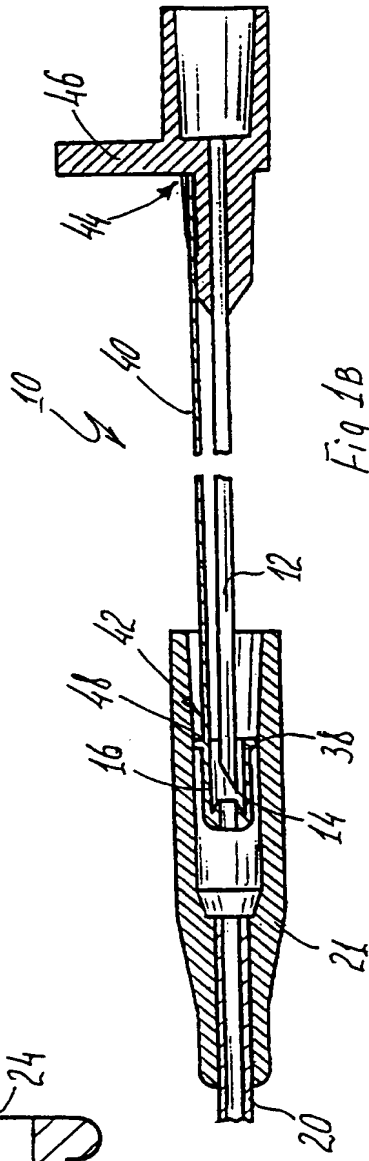


Fig 1B

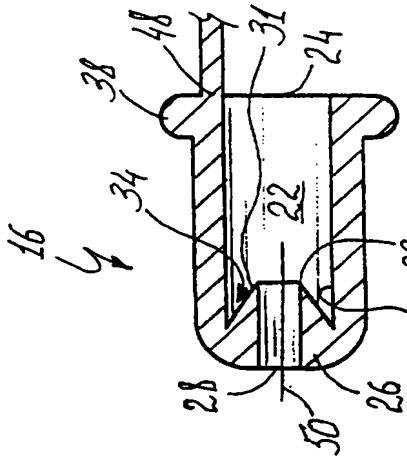


Fig 2

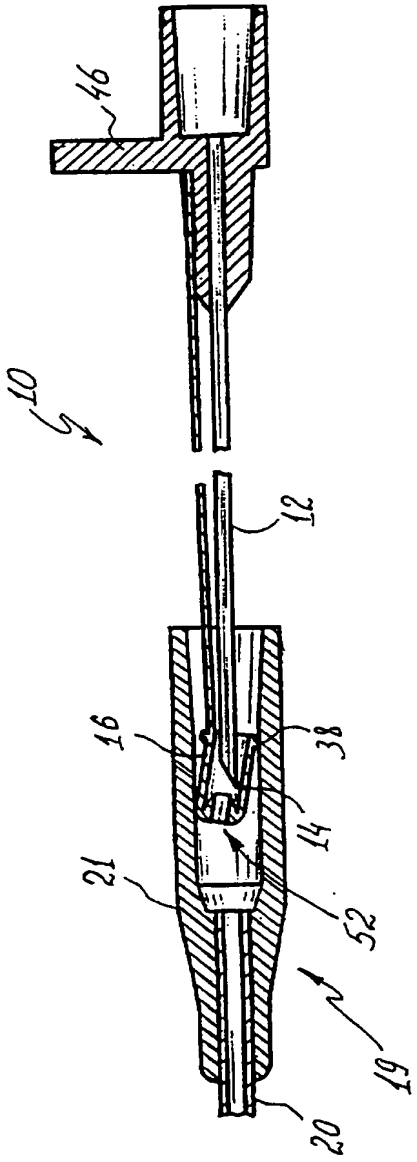


Fig 1c

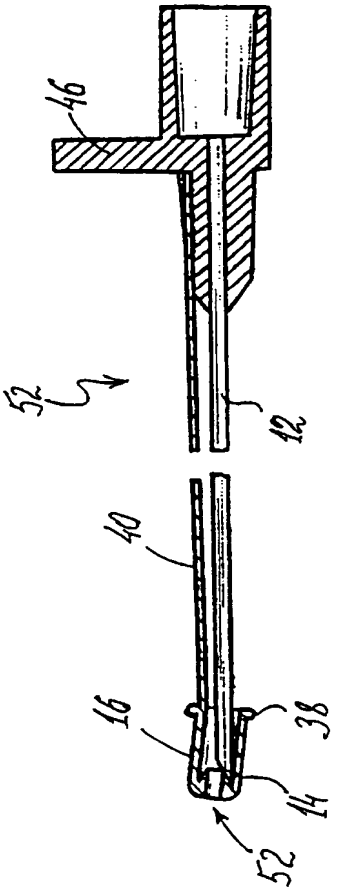


Fig 1D

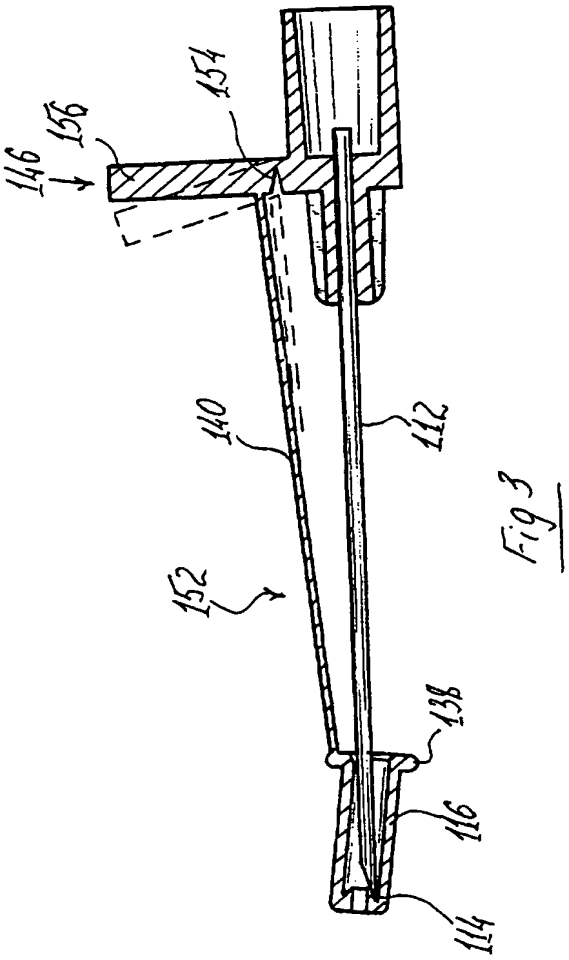


Fig 3

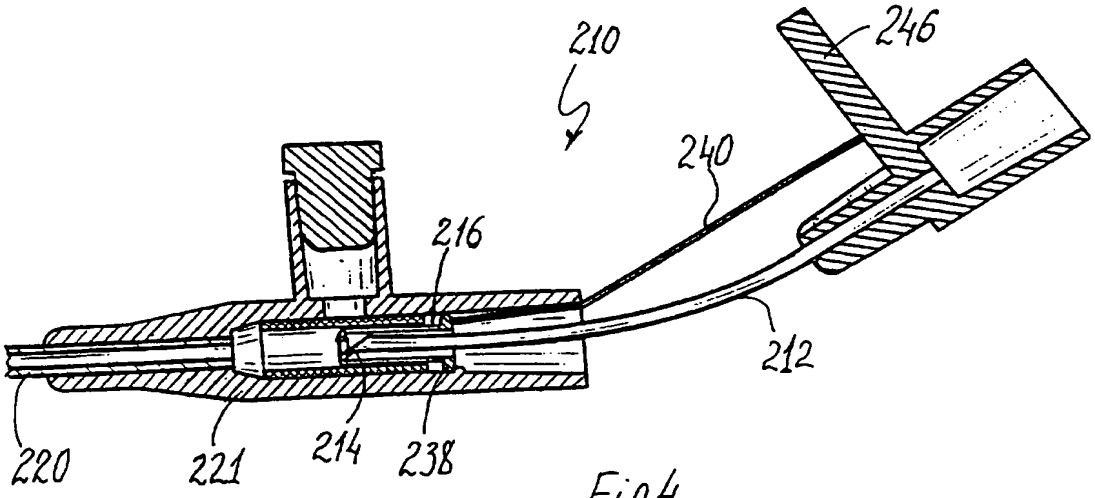


Fig 4.

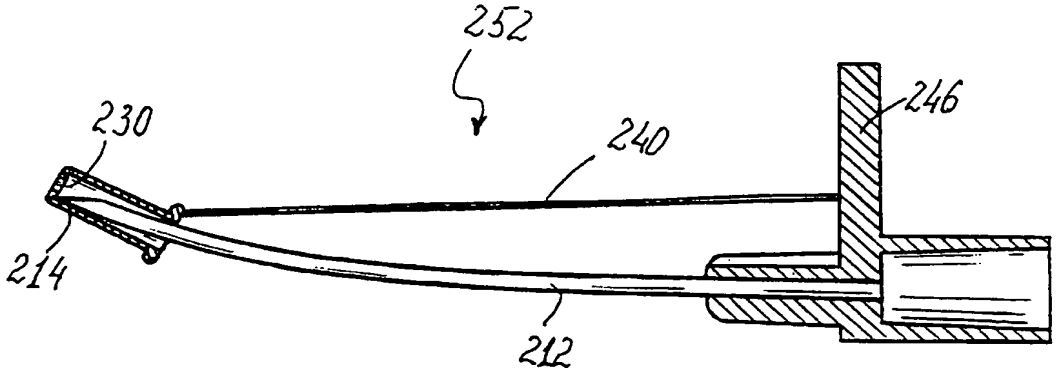


Fig 5

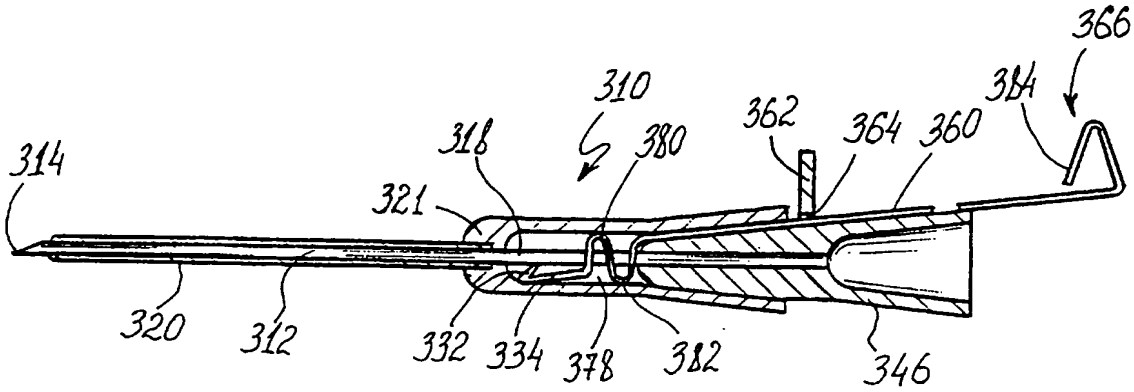

366
310
384
362
364
360
318
380
314
321
320
312
332
334
378
382
346

Fig 6

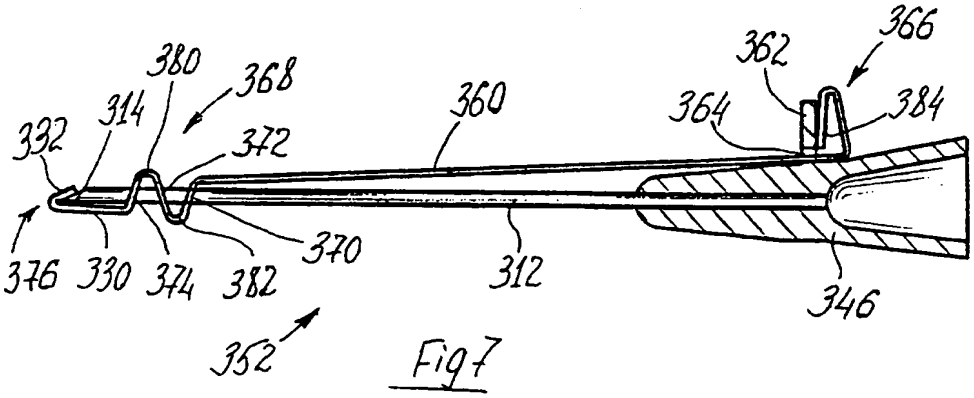

366
362
380
368
360
364
384
314
332
372
376
330
374
382
370
312
346
352

Fig 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL97/00155

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 5/00, 32, 178
US CL :604/110, 164, 192, 198
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/110, 162, 164, 187, 192, 198, 263

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,312,371 A (DOMBROWSKI et al) 17 May 1994, entire document.	1-22
A	US 5,478,313 A (WHITE) 26 December 1995, entire document.	1-22
A	US 5,221,266 A (KASTAN) 22 June 1993, entire document.	1-22
A	US 5,013,305 A (OPIE et al) 07 May 1991, see entire document.	1-22

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 AUGUST 1997	18 SEP 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer ROBERT V. RACUNAS Telephone No. (703) 308-3589

Form PCT/ISA/210 (second sheet)(July 1992)*